Examiner for acknowledging that the subject matter of claim 10 is allowable matter and free of the cited prior art.

Claim 3 is objected to under 37 C.F.R. § 1.75(c) for failure to further limit the subject matter of a previous claim. Claim 3 is amended herein to make it independent by incorporating the limitations of claim 1, from which claim 3 depended. Support for this amendment can be found at least at page 3, lines 31-33 of the specification and in claim 1. Applicant submits that claim 3 as amended overcomes the objection under 37 C.F.R. § 1.75(c), and respectfully requests that the Examiner withdraw the objection.

Claim rejections under 35 U.S.C. § 102:

Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tine *et al.*, *Infection and Immunity*, 64(9): 3833-3844, September 1996. The Office action alleges that Tine *et al.* teach a recombinant protein comprising peptides from two or more stages in a life cycle of *Plasmodium falciparum* that appears to render the disclosed epitope sequences inherent. Applicant submits herewith a Second Declaration under 37 C.F.R. § 131 of Dr. Ya Ping Shi ("Second Declaration") to overcome Tine *et al.* The Second Declaration submitted herewith is unsigned; Applicant will forward a signed copy of the Declaration in a separate communication when it is received. The Second Declaration provides evidence that the inventors of the current application reduced the invention that is the subject matter of the current application to practice prior to September 1996, the effective date of Tine *et al.* Specifically, the Second Declaration refers to evidentiary Exhibits A and B submitted herewith, which were previously submitted in support of the First Declaration of Dr. Shi under 37 C.F.R. § 131 ("First Declaration") with Applicant's June 11, 2002 amendment and response. The exact dates of Exhibits A and B have been redacted, but are prior to the September 1996 effective date of Tine *et al.* 

Applicant submits that the Second Declaration, which references data set forth in Exhibits A and B of the First Declaration, provides sufficient evidence that the inventors of the current application reduced the invention that is the subject matter of the claims of the current application to practice prior to September 1996, the effective date of Tine *et al.* Hence,

WDN/TMH/DJZ:kam 01/02/03 155530 **PATENT** 

Applicant has complied with the requirements of MPEP § 715 to overcome Tine et al., and requests that the rejection of claims 1-3, 5 and 6, based upon this reference, be withdrawn.

Claim rejections under 35 U.S.C. § 103:

Claims 1 and 3-6 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tine et al., in view of Schmitt et al. (Molecular Biology Reports 18: 223-230, 1993). As discussed above, a rejection based on Tine et al. should not be sustained in view of the Second Declaration submitted herein, which shows that the inventors of the current application reduced the invention that is the subject matter of the claims of the current application to practice prior to the effective date of Tine et al.

Schmitt et al. teach affinity purification of using histidine-tagged recombinant proteins, but do not teach a recombinant protein comprising antigenic epitopes of Plasmodium falciparum as disclosed in the current application. Therefore, Applicant submits that Schmitt et al. does not render the claims of the current application obvious and request that the rejection based upon this reference be withdrawn.

## **CONCLUSIONS**

It is respectfully submitted that the present claims are in condition for allowance. If it may expedite issuance of these claims, the Examiner is invited to call the undersigned patent attorney at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

William D. Noonan, M.D.

Registration No. 30,878

One World Trade Center, Suite 1600 121 S.W. Salmon Street

Portland, Oregon 97204

Telephone: (503) 226-7391 Facsimile: (503) 228-9446

## Marked-up Version of Amended Claims Pursuant to 37 C.F.R. §§ 1.121(b)-(c)

- 1. (<u>reiterated</u>) A recombinant protein comprising peptides from two or more stages in a life cycle of *Plasmodium falciparum*, wherein each peptide comprises an antigenic epitope comprising the amino acid sequence as set forth as SEQ ID NOs: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, or 25.
- 3. (amended) The protein of claim 1, A recombinant protein comprising peptides from two or more stages in a life cycle of *Plasmodium falciparum*, wherein the amino acid sequence encoding the protein comprises the amino acid sequence set forth as comprising the amino acid sequence of SEQ ID NO: 2.
- 4. (<u>reiterated</u>) The protein of claim 1, further comprising a signal peptide polyhistidine, and a T-cell helper epitope.
- 5. (<u>reiterated</u>) The protein of claim 1, wherein the stages are one or more of sporozoite stage, liver stage, blood stage or sexual stage.
- 6. (<u>reiterated</u>) The protein of claim 5, comprising at least one antigenic epitope from each of the sporozoite, liver, blood, and sexual stages of *Plasmodium falciparum* life cycle.
- 10. (<u>reiterated</u>) A protein composition comprising the recombinant protein of claim 1, in a pharmaceutically acceptable carrier.